UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,373	05/25/2001	William F. Krise	KRISE 1A	1608

7590 02/24/2006

Office of Counsel Code OC4
Naval Surface Warfare Center
Indian Head Division
101 Strauss Ave., Bldg. D-326
Indian Head, MD 20640-5035

EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,373	KRISE ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-12,15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-12,15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed November 25, 2005 is acknowledged and has been entered.

Drawings

2. The drawings were received on November 25, 2005. These drawings are acceptable.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 7-9, 11, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Zarling et al (US 5,674,698).

Zarling et al reference teaches an apparatus comprising a handheld probe and a container with sample fluid D8 (i.e. sample holder), wherein the handheld probe comprises a diode excitation laser D3 (i.e. light source; laser diode), a photodiode detector D5 (i.e. a detector within the sample holder), and a capture surface D9 within

wick D2 (i.e. analysis area within the uptake channel), wherein the capture surface comprises antibodies covalently linked to the inner surface of the tube wall, (i.e. matrix activated by binding a capture molecule to the matrix). See column 40, lines 5-30 and Figure 29. In addition, Zarling et al teach that the excitation source can be a near-infrared laser diode (i.e. light source that emits near infrared wavelengths) and luminescent materials used as labels which can be linked to a biological probe (i.e. a reagent tag that fluoresces when subject to light emissions; laser dye). Furthermore, Zarling et al teach that the apparatus can have a fiber optic probe (i.e. optical system comprising a lens). See Figure 23. See column 5, lines 40-59.

With regards to claim 9, Zarling et al teach bandpass filters for emission bands. See column 37, line 18.

With regards to claim 11, Zarling et al teach that the capture surface is constrained within a region D9 on the inner surface of the capillary having silanized surfaces. See column 30, lines 5-30 and Figure 29. The areas on either side of the region are not silanized and would therefore pose a physical barrier to antibodies that attach only to silanized areas.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zarling et al (US 5,674,698) in view of Wohlstadter et al (US 6,066,448).

Zarling et al reference has been disclosed above, and additionally teaches a photodiode detector connected to a display. See Figure 29. However, Zarling et al fail to teach that the photodiode is coupled to a LCD.

Wohlstadter et al teach an array of LCD shutters attached to photodiode detectors, in order to provide a mechanism for controlling errors due to electrical noise inherent in light detectors. See column 25, lines 38-43 and column 26, lines 6-25.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Zarling et al with an array of LCD shutters attached to photodiode detectors, as taught by Wohlstadter et al, in order to provide a mechanism for controlling errors due to electrical noise inherent in light detectors. The LCD shutters of Wohlstadter et al provide the advantage of reducing errors in the photodiode detectors of Zarling et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the LCD shutters of Wohlstadter et al, in the apparatus of Zarling et al, since Zarling et al teach photodiode detectors, and the LCD shutters of Wohlstadter et al are capable of coupling to photodiode detectors.

9. Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zarling et al (US 5,674,698) in view of Klose et al (US 4,515,889).

Zarling et al reference has been disclosed above, but fails to teach that the analysis target area extends from an end of the uptake channel that is free of solid phase.

Klose et al reference teaches a flow channel having chambers 43-49 connected to cuvette 51 such that sample liquid contacts the chambers prior to the cuvette, and wherein the chambers comprise different immunologically active bodies, in order to

provide a channel that can perform affinity chromatography prior to the analysis of the sample in the cuvette. See column 3, line 47 to column 4, line 8; column 8, lines 3-27; and Figure 5.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Zarling et al with a flow channel having chambers 43-49 connected to cuvette 51 such that sample liquid contacts the chambers prior to the cuvette, and wherein the chambers comprise different immunologically active bodies, as taught by Klose et al, in order to provide a channel that can perform affinity chromatography prior to the analysis of the sample in the cuvette. Affinity chromatography can prevent unwanted particles from entering the detection area, thereby reducing potential noise or errors in measurement. The motivation for providing a more effective measuring means therefore provides motivation to combine the arrangement of the chambers and cuvette, as taught by Klose et al, in the apparatus of Zarling et al. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the chambers and cuvette of Klose et al, in the apparatus of Zarling et al, since Zarling et al teach sections of a flow channel that can contain immobilized capture agents (i.e. capture surface D9), and the chambers of Klose et al are of the same type of sections in Zarling et al. Furthermore, because the combination of Zarling et al and Klose et al alter the position of the detection area of Zarling et al, the optical detection means would have to be modified to emit and receive fluorescent signals at a point further into chamber D1 since it is conceivable that the current position of the capture surface D9 would be replaced by

chambers 43-49. However, it would not be outside the knowledge of one of ordinary skill in the art to simply rearrange the light source and detector to emit and detection at another position within the apparatus since doing so does not require anything more than routine skill in the art.

With respect to claim 15, since the cuvette of Klose et al would be placed within chamber D1 of Zarling et al, the extension of the flow channel from the chromatography chambers 43-49 is considered to be the claimed "tube connected to the side of the uptake channel to extend the uptake channel into the reservoir". Such an arrangement would therefore necessarily teach the claimed limitation that the "reservoir extending from a side of the uptake channel", which is considered to be D1, has "a diameter larger than a diameter of the uptake channel".

10. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zarling et al (US 5,674,698) in view of Ekong et al (Journal of Immunological Methods, 1995).

Zarling et al reference has been taught above, and additionally teaches that the phosphor-probe conjugates are impregnated in a wick that is contacted with sample in liquid (i.e. laser dye is soluble in water; negative charge), and that the probe-label conjugate can be formed through electrostatic interactions. See column 40, lines 31-36; column 10, lines 60-61; and Figure 29. However, Zarling et al fail to teach that the laser dye binds to gamma globulin.

Ekong et al reference teaches labeled IgG as a secondary antibody in an immunoassay, in order to detect botulinum neurotoxin type A. See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Zarling et al with labeled IgG as a secondary antibody in an immunoassay, as taught by Ekong et al, in order to detect botulinum neurotoxin type A. The labeled IgG of Ekong et al would provide the advantage of detecting a potent neurotoxin in the apparatus of Zarling et al. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including labeled IgG, as taught by Ekong et al, in the apparatus of Zarling et al, since Zarling et al teach labeled antibodies as probes, and the labeled IgG of Ekong et al is a secondary antibody, which is considered to be a type of probe.

11. Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zarling et al (US 5,674,698) in view of Ekong et al (Journal of Immunological Methods, 1995), and further in view of Hammock et al (US 6,342,395 B1).

Zarling et al and Ekong et al references have been disclosed above, but fail to teach that the laser dye has the formula $C_{45}H_{48}N_3O_{13}S_5Na_3$.

Hammock et al reference teaches NN382 dyes, in order to provide fluorescers in the near IR wavelength range of about 790 nm. See column 6, lines 24-32. Hammock et al also teach that the fluorescers are labels for immunoasssays. See column 5, line 1 to column 6, line 22.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Zarling et al and Ekong et al with NN382 dyes, as taught by Hammock et al, in order to provide light-sensitive fluorescers in the near IR wavelength range of about 790 nm. The advantage of providing fluorescers in a specific IR wavelength provides the motivation to combine the NN382 dye of Hammock et al with the apparatus of Zarling et al and Ekong et al. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the NN382 dye of Hammock et al in the apparatus of Zarling et al and Ekong et al, since Zarling et al and Ekong et al teach labels that bind to biomolecules, and the NN382 dye of Hammock et al also bind to biomolecules.

Response to Arguments

12. Applicant's arguments, see page 10 of the response, filed November 25, 2005, with respect to the preamble of claims 7 and 12 have been fully considered and are persuasive. The rejection under 35 USC 112, 1st paragraph of claims 7-12, 15, and 17-20 have been withdrawn.

13. On pages 11-13 of the response, Applicants traverse the rejection of the pending claims under 35 USC 102(b) as being anticipated by Zarling et al. Specifically, Applicants argue several points:

(1) Applicants argue that the activated matrix of the present invention differs from the capture surface D9 of Zarling, since Zarling teaches fluid flow ***across*** the capture surface whereas the claimed invention has sample fluid that flows ***through*** the activated matrix, which increases the likelihood of capture. See page 11, last paragraph to page 12, 2nd paragraph.

(2) Regarding newly amended claim 12, Applicants argue that the analysis target area extends from the end of the uptake channel and is free of solid phase, whereas Zarling teaches that capture surface D9 necessarily has a solid phase. See page 12, 3rd paragraph to page 13, 2nd paragraph.

(3) Regarding claim 15, Applicants state that the bubble of Zarling is not similar to the bubble of the present invention since Zarling teaches that the bubble is enclosed by the tube surrounding the capillary wick D2, whereas in the claimed invention, the bubble is formed at the end of the tube that extends the from uptake channel.

(4) Applicants invoke Rule 1.131 and state that a declaration was submitted to indicate that the present invention was actually reduced to practice between September 1998 and March 1999, which precedes the publication date of the Baars article.

Applicants' arguments on the first and third points above have been fully considered, but are not found convincing. With respect to Applicants' first point above, the claim language in independent claims 7 and 12 only require that a matrix be

present, and does not specify the manner in which the matrix is structured such that liquid can only flow in a certain arrangement with respect to the matrix. In addition, the specification only mentions the term "matrix" and does not actually indicate that the term refers to a substance such as nitrocellulose or a membrane that would require liquid to flow through it. Therefore, Applicants' argument that the capture surface D9 of Zarling does not teach the claimed "matrix" is not convincing due to a lack of support in the specification that limits the matrix to a material that requires liquid flow through it, and also to the fact that the capture surface of Zarling is capable of performing the exact claimed function.

With respect to Applicants' third argument above, the bubble of claim 15 is recited as a method step "wherein a bubble to be analyzed ***is formed*** on an end of the tub, the bubble comprising the analysis target area". Since the parent claim is directed towards an apparatus, method steps in dependent claims are considered to be an intended use of the apparatus. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since Zarling et al teach that the flow channel produces liquid flow through wicking, liquid is draw up the channel by surface tension through capillary flow. Since Zarling shows that the flow channel can comprise a wicking means throughout the length of the entire channel, the channel is therefore capable of allowing a bubble to be formed at the end in section D1, where the wicking means ends.

With respect to Applicants' second point above, since claim 12 has been amended, Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

With respect to Applicants' fourth point above, Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Claims 7-12, 15, and 17-20 are rejected.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y. Lum
Patent Examiner
Art Unit 1641

LYL

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/17/06